

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>TRCA-004</b>
		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/582,047</b>
INTERNATIONAL APPLICATION NO. <b>US2004/041308</b>	INTERNATIONAL FILING DATE <b>12/10/2004</b>	PRIORITY DATE CLAIMED <b>December 11, 2003</b>
<b>TITLE OF INVENTION METHODS AND COMPOSITIONS FOR THE TREATMENT OF PROLACTIN-RECEPTOR RELATED DISORDERS</b>		
<b>APPLICANT(S) FOR DO/EO/US Ross G. CLARK</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office(RO/US) 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). <b>Items 11 to 20 below concern document(s) or information included:</b> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/582,047</b>	INTERNATIONAL APPLICATION NO. <b>US2004/041308</b>	ATTORNEY'S DOCKET NUMBER <b>TRCA-004</b>
20. Other items or information: <b>PTO Form SB08a; 14 References ; Return Postcard</b>		
The following fees have been submitted		CALCULATIONS      PTO USE ONLY
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)).....\$300		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
If the written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$0 All other situations .....\$200		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion prepared by ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....\$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....\$400 All other situations .....\$500		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
<b>TOTAL OF 21, 22 and 23 =</b>		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.82(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is <b>\$250</b> for each additional 50 sheets of paper or fraction thereof.		<div style="display: flex; justify-content: space-between;"> <span></span> <span></span> </div>
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)
- 100 =	/50 =	X \$250
Surcharge of <b>\$130.00</b> for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
CLAIMS	NUMBER FILED	NUMBER EXTRA
Total Claims	- 20 =	x \$50
Independent Claims	- 3 =	x \$200
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ \$360
<b>TOTAL OF ABOVE CALCULATIONS =</b>		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.		<div style="display: flex; justify-content: space-between;"> <span></span> <span></span> </div>
<b>SUBTOTAL =</b>		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
<b>TOTAL NATIONAL FEE =</b>		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property		<div style="display: flex; justify-content: space-between;"> <span>\$</span> <span></span> </div>
<b>TOTAL FEES ENCLOSED =</b>		<div style="display: flex; justify-content: space-between;"> <span>\$ 0.00</span> <span></span> </div>
		<div style="display: flex; justify-content: space-between;"> <span>Amount to be refunded:</span> <span>\$0.00</span> </div>
		<div style="display: flex; justify-content: space-between;"> <span>Amount to be charged:</span> <span>\$0.00</span> </div>

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- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. 50-0815 in the amount of \$\_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees (other than excess claim fees unless indicated above) which may be required, or credit any overpayment to Deposit Account No. 50-0815. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

**Bozicevic, Field & Francis, LLP**  
**1900 University Avenue**  
**Suite 200**  
**East Palo Alto, California 94303**

\_\_\_\_\_  
SIGNATURE

**Paula A. Borden**

\_\_\_\_\_  
NAME

**42,344**

\_\_\_\_\_  
REGISTRATION NUMBER

**Express Mail No. EV 954 014 400 US**

<b>INFORMATION DISCLOSURE STATEMENT</b>  Address to: Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	TRCA-004
	First Named Inventor	Ross G. CLARK
	Application Number	10/582,047
	Confirmation No.	9278
	Filing Date	December 10, 2004
	Group Art Unit	1642
	Examiner Name	
	Title: "METHODS AND COMPOSITIONS FOR THE TREATMENT OF PROLACTIN-RECEPTOR RELATED DISORDERS"	

Sir:

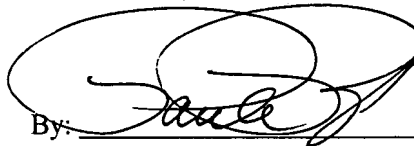
This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form PTO-SB/08A listing the references and copies of the cited references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C. §102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. TRCA-004 may be charged thereon.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

By: 

Paula A. Borden  
Registration No. 42,344

Date: July 31, 2007

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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/582,047		
		Filing Date	December 10, 2004		
		First Named Inventor	Ross G. CLARK		
		Art Unit	1642		
		Examiner Name			
Sheet	1	of	2	Attorney Docket Number	TRCA-004

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BATAILLE-SIMONEAU <i>et al.</i> (1996), "Expression of Prolactin Receptors in Human Osteosarcoma Cells", <i>Biochemical and Biophysical Research Communications</i> 229(1):323-328	
		BHATAVDEKAR <i>et al.</i> (2000), "Prolactin As A Local Growth Promoter in Patients with Locally Advanced Tongue Cancer: GCRI Experience" <i>Head &amp; Neck</i> 22:257-264	
		BINART <i>et al.</i> , (2000) "Mammary Gland Development and the Prolactin Receptor" <i>Adv. Exp. Med. Biol.</i> 480:85-92	
		BLANKENSTEIN <i>et al.</i> (1988), "Hormone Receptors in Human Prostate Cancer" <i>Scand. J. Urol. Nephrol. Suppl.</i> 107:39-45	
		BONNETERRE <i>et al.</i> (1990), "Biological and Clinical Aspects of Prolactin Receptors (PRL-R) in Human Breast Cancer, <i>Journal Steroid Biochem. Mol. Biol.</i> 37(6):977-981	
		CICCARELLI <i>et al.</i> , (2001), "Hyperprolactinaemia and prolactine binding in benign intracranial tumours", <i>Journal of Neurosurgical Sciences</i> 45(2):70-74	
		GARCIA-CABALLERO <i>et al.</i> , (2000), "Increased Expression of Growth Hormone and Prolactin Receptors in Hepatocellular Carcinomas", <i>Endocrine</i> 12(3):265-71	
		GOFFIN <i>et al.</i> , (1999), "From the molecular biology of prolactin and its receptor to the lessons learned from knockout mice models", <i>Genetic Analysis</i> 15(3-5):189-201	
		JIN <i>et al.</i> , (2007), "Prolactin Receptor Messenger Ribonucleic Acid in Normal and Neoplastic Human Pituitary Tissues", <i>Journal of Clinical Endocrinology and Metabolism</i> 82(3): 963-968	
		KINET <i>et al.</i> (1999) "Biological Properties of Human Prolactin Analogs depend Not Only on Global Hormone Affinity, but Also on the Relative Affinities of Both Receptor Binding Sites" <i>The Journal of Biological Chemistry</i> . 274:26033-26043	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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			Application Number	10/582,047	
			Filing Date	December 10, 2004	
			First Named Inventor	Ross G. CLARK	
			Art Unit	1642	
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	TRCA-004

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MOL <i>et al.</i> , (2000) "Progestin-induced Mammary Growth Hormone (GH) Production" <i>Adv. Exp. Med. Biol.</i> 480:71-76	
		MUCCIOLI <i>et al.</i> , (1997) "Prolactin receptors in human meningiomas: characterization and biological role" <i>Journal of Endocrinology</i> 153(3):365-371	
		NOWAK <i>et al.</i> , (1999), "Prolactin IS an Autocrine or Paracrine Growth Factor for Human Myometrial and Leomyoma Cells" <i>Gynecologic and Obstetric Investigation</i> 48(2):127-132	
		SHIU (1979) "Prolactin Receptors in Human Breast Cancer Cells in Long-term Tissue Culture", <i>Cancer Research</i> , 39, 4381-4386	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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